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Supreme Court of the United States

CAROL M. BROWNER, ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY, *ET AL.*,

Petitioners,

v.

AMERICAN TRUCKING ASSOCIATIONS, INC., *ET AL.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF *AMICI CURIAE* OF GARY E. MARCHANT, CARY COGLIANESE, DANIEL M. BYRD III, GAIL CHARNLEY, MAUREEN L. CROPPER, E. DONALD ELLIOTT, DAVID L. FAIGMAN, JAMES K. HAMMITT, JAMES E. KRIER, WILLIAM H. LASH III, ROGER O. McCLELLAN, THOMAS W. MERRILL, LARS NOAH, JOYCE E. PENNER, ROBERT PHALEN, JEFFREY J. RACHLINSKI, JOSEPH SANDERS, ROBERT N. STAVINS, JONATHAN B. WIENER and JAMES D. WILSON IN SUPPORT OF RESPONDENTS

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INTEREST OF THE *AMICI*

Amici are professors and scientists with scholarly or professional interests in the intersection of law and science. The various *amici* have taught, researched, and published on issues involving law, science, and policy. Brief summaries of the qualifications and affiliations of the individual *amici* are provided at the end of this brief.

Amici have an interest in seeing that the Court is informed on the appropriate use and limitations of science in setting national ambient air quality standards (NAAQS) under the Clean Air Act. While *amici* support reliance on science to assess the risks of alternative air quality standards, science alone cannot provide a principled justification for setting such standards.

Amici file this brief solely as individuals and not on behalf of the institutions with which they are affiliated. In addition, *amici* take no position on the merits of the specific air quality standards at issue in this case. Rather, their views address the broader question of the role of science in the process by which the U.S. Environmental Protection Agency (EPA) sets air quality standards.[1]

BACKGROUND

The Clean Air Act calls for the EPA Administrator to use her "judgment" to select a primary NAAQS that is "requisite to protect the public health" based on the criteria document and allowing "an adequate margin of safety." 42 U.S.C. §7409(b)(1). The statute also specifies that the criteria document shall "reflect the latest scientific knowledge" about

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[1] Pursuant to Rule 37.6 of the Rules of this Court, *amici* state that no person or entity, other than the individual *amici*, authored this brief in whole or in part, or made any monetary contribution to the preparation or submission of this brief. Letters of consent to the filing of this brief from all parties have been lodged with the Clerk of the Court pursuant to Rule 37.3.

the public health and welfare[2] effects of the pollutant in question. *Id.* § 7408(a)(2).

At every step in this proceeding, including before this Court, EPA has purported to rely exclusively on scientific factors to justify its selection of revised NAAQS for ozone and particulate matter (PM). Even though EPA appears to acknowledge in its rulemaking preambles that setting air quality standards is a "policy choice,"[3] the only criteria it identifies for making such choices are scientific ones.

In its brief filed in this Court, EPA identified three types of limitations on its NAAQS rulemaking discretion which the Agency argues satisfy the "intelligible principle" requirement. Brief for Petitioner U.S. EPA, No. 99-1257, at 23-24 (July 21, 2000) (hereinafter "EPA Br."). The three limitations are the criteria documents reflecting "the latest scientific knowledge," the advice from the EPA's Clean Air Scientific Advisory Committee (CASAC), and the rulemaking requirements of section 307(d) of the Clean Air Act. The latter "limitation" is procedural only, while the first two factors emphasize scientific inputs.

Likewise, in the NAAQS rulemakings, EPA justified the selection of its NAAQS standards based exclusively on health effects and scientific criteria. For example, EPA claimed to select its ozone standard based solely on "public health policy judgments in addition to determinations of a strictly scientific nature," with assessments of risk playing a "central role in identifying an appropriate level." 62 Fed. Reg. at 38,863 (quotation omitted). The only type of public health "policy

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[2] Under the Clean Air Act, "welfare" effects refer to non-human biological and physical effects, not monetary measures of impacts as economists use the term.

[3] EPA, Ozone Final Rule, 62 Fed. Reg. 38,856, 38,857 (July 18, 1997); EPA, PM Final Rule, 62 Fed. Reg. 38,652, 38,653 (July 18, 1997).

judgments" that EPA identified were factors such as the nature and severity of health effects, the types of health evidence, the kind and degree of uncertainties involved, and the size and nature of the sensitive populations at risk. *Id.* at 38,883; EPA Br. at 5.

Finally, in testimony to Congress on the proposed ozone and PM NAAQS, EPA's Administrator stated that "[a]s you can see from the description of the process I went through to choose proposed levels on ozone and particulate matter, the focus has been entirely on health, risk, exposure and damage to the environment." Testimony of Carol M. Browner, EPA Administrator, Before the Subcomm. on National Economic Growth, Natural Resources, and Regulatory Affairs of the House Comm. on Government Reform and Oversight (Apr. 23, 1997) (1997 WL 10571215). In defending her selection of the proposed standards to the public, the Administrator reportedly claimed that "I think it is not a question of judgment, I think it is a question of science." *Air Quality Standards: Science-Driven Ozone, PM Proposals Will Be Finished by July 19, EPA Says*, 27 ENV'T REP. (BNA) 2068 (Feb. 14, 1997).

SUMMARY OF ARGUMENT

Throughout this proceeding, EPA has identified no policy or normative criteria to justify its NAAQS standards, thus suggesting that science alone can be used to determine the appropriate air quality standard. Science plays a critical, indeed essential, role in evaluating the risks of possible air quality standards being considered for adoption by EPA. However, science by itself cannot provide the justification for selecting a particular air quality standard. Especially in setting standards for non-threshold pollutants, such as in this case, scientific evidence cannot alone indicate where the standard should be set, since any level above zero will cause some health effects. To provide a principled and consistent basis for justifying the setting of such standards at some level above

zero, EPA must articulate other factors -- whether they be costs or other policy criteria -- to guide its decisions on where to set national ambient air quality standards.

ARGUMENT

As in the proceedings below, EPA's brief filed in this Court identifies no factors or criteria other than scientific evidence to guide its selection of revised primary national ambient air quality standards for ozone and particulate matter. While science[4] is a critical, indeed essential, input in developing standards, science alone cannot provide an "intelligible principle" to guide policy decisions about the level at which to set EPA's revised NAAQS.

I. SCIENCE ALONE CANNOT PROVIDE A BASIS FOR RISK MANAGEMENT DECISIONS

Science has played a prominent and important role in agency regulatory decisions, as well as in judicial review of those decisions. Such reliance on science is justified given the advances that science has made over the past few decades in understanding environmental risks. Yet, purporting to rely solely on science to answer questions science is not designed to address is as misguided as it would be to disregard relevant scientific information. Science plays an appropriate and central role in regulatory agencies' assessments of risk, by providing systematic and reliable knowledge about the world. In contrast, risk management decisions, including decisions on setting health standards, are ones for which science alone cannot provide a principled foundation.

[4] The term "science" as used throughout this brief refers to the natural sciences.

A. Science Describes and Explains

As this Court recently noted, science is "a process for proposing and refining theoretical explanations about the world." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993) (citing Brief for American Association for the Advancement of Science et al. as *Amici Curiae* 7-8). As such, science seeks to supply verifiable descriptions of, and explanations about, what *is*, rather than imposing judgments about what *should be*. Science describes, it does not prescribe.

B. Risk Management Prescribes

In the context of health and environmental risks, science plays a critical role in identifying, describing, and quantifying risks, but it does not tell us whether such risks are acceptable or should be reduced. The National Academy of Sciences (NAS) recognized this distinction in its influential 1983 report known as the "Red Book," which established a framework for risk analysis on which regulatory agencies continue to rely today. NATIONAL ACADEMY OF SCIENCES/NATIONAL RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983) ("NAS Red Book").

The NAS distinguished *risk assessment* from *risk management*. It defined risk assessment as "the characterization of the potential adverse health effects of human exposures to environmental hazards." *Id.* at 18. Risk assessment is based on scientific information, supplemented with what have been termed "risk assessment policy" judgments to bridge gaps and uncertainties in the scientific evidence. *Id.* at 37.[5] Risk assessment is considered to be

[5] Such risk assessment policy judgments include factors such as which health effects to consider and to group together, the type of models and assumptions to use in the risk assessment, how to extrapolate data from one small segment of a population to the entire population, and how to compute

(continued...)

predominantly -- though not exclusively[6] – based on scientific evidence and analysis.

Risk management, on the other hand, is "an agency decision-making process that entails consideration of political, social, economic, and engineering information with risk-related information to develop, analyze, and compare regulatory options and to select the appropriate regulatory response to a potential chronic health hazard." NAS Red Book at 18-19. Risk management "necessarily requires the use of value judgments on such issues as the acceptability of risk and the reasonableness of the costs of control." *Id.* at 19.[7] As a subsequent National Research Council report reiterated, "science alone can never be an adequate basis for a risk decision" because "[r]isk decisions are, ultimately, public policy choices."[8] This Court has likewise recognized that the

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[5] (...continued)
and present uncertainties. NAS Red Book at 29-33. These risk assessment policy judgments are comparable to the "public health policy judgments" that EPA identified as a basis for its NAAQS decisions. *See* 62 Fed. Reg. at 38,883; *supra* pp. 2-3.

[6] *E.g.*, Sheila Jasanoff, *Contested Boundaries in Policy-Relevant Science*, 17 SOC. STUD. SCI. 195, 211 (1987) (noting that analysts have "agreed that very little in a typical risk assessment could be labeled as pure science"); DANIEL M. BYRD III & C. RICHARD COTHERN, INTRODUCTION TO RISK ANALYSIS: A SYSTEMATIC APPROACH TO SCIENCE-BASED DECISION MAKING 6-8, 330-34 (2000) (risk assessment inherently and inevitably involves some judgment).

[7] *See also* Craig N. Oren, *Run Over By* American Trucking *Part I; Can EPA Revive Its Air Quality Standards?*, 29 ENVT'L L. REP. 10,653, 10,660 (Nov. 1999) ("the decision of who should be protected, and what effects they should be protected against, is an ethical decision, not a scientific one").

[8] NATIONAL RESEARCH COUNCIL, UNDERSTANDING RISK: INFORMING DECISIONS IN A DEMOCRATIC SOCIETY 26 (1996). This report cautioned against too strict of a separation between risk assessment and risk management, because non-scientific deliberative and policy factors can also be relevant to risk assessment. *Id.* at 34.

setting of health and environmental standards is primarily a policy rather than scientific undertaking.[9]

Risk assessment is therefore understood to be predominantly (but not exclusively) a scientific undertaking, whereas risk management decisions, including the selection of standards, require making value judgments that extend beyond the scope of science.[10] The National Academy recommended that regulatory agencies should "maintain a clear conceptual distinction between assessment of risks and consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies." NAS Red Book at 7.

EPA has endorsed and relied on the NAS's distinction between risk assessment and risk management.[11] For example,

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[9] In the Court's 1980 review of OSHA's benzene occupational exposure standard, Justice Marshall's dissenting opinion stated: "[W]hen the question involves determination of an acceptable level of risk, the ultimate decision must necessarily be based on considerations of policy as well as empirically verifiable facts. Factual determinations can at most define the risk in some statistical way; the judgment whether that risk is tolerable cannot be based solely on a resolution of the facts." Industrial Union Dep't, AFL-CIO v. American Petroleum Inst., 448 U.S. 607, 706 (1980). The plurality opinion quoted Justice Marshall's statement, and then responded: "We agree. Thus, while the Agency must support its finding that a certain level of risk exists by substantial evidence, we recognize that its determination that a particular level of risk is 'significant' will be based largely on policy considerations." *Id.* at 655 n.62 (plurality opinion).

[10] *See also* WILLIAM W. LOWRANCE, OF ACCEPTABLE RISK 75-76 (1976) ("Determining safety, then, involves two extremely different kinds of activities... *Measuring risk* - measuring the probability and severity of harm–is an empirical, scientific activity; *Judging safety*– judging the acceptability of risks, is a normative, political activity.").

[11] *E.g.*, EPA, Science Policy Council, *Guidance for Risk Characterization* 2 (Feb. 1995) (available at http://www.epa.gov/ORD/spc/rcguide.htm) ("In

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in a recent EPA guidance on conducting risk analysis, EPA directed that agency staff should clearly separate risk assessment from risk management, with risk assessment involving the selection, evaluation and presentation of "scientific information," but not "decisions on the acceptability of any risk level for protecting public health or selecting procedures for reducing risks." EPA, *Risk Characterization Guidance*, *supra* note 11, at 3.

In contrast, EPA noted that risk management decisions should be based on, to the extent permissible, a consideration of "technological feasibility (e.g., treatability, detection limits), economic, social, political, and legal factors," in addition to the output of the risk assessment process. *Id.* According to EPA, "risk assessors and risk managers should understand that the regulatory decision is usually not determined solely by the outcome of the risk assessment." *Id.* In order to make risk assessments "transparent," EPA has further stated that it is important "that conclusions drawn from the science are identified separately from policy judgments and risk management decisions." 63 Fed. Reg. 43,756, 43,769 (Aug. 14, 1998).

3. Agencies Can Use Science as a "Charade"

Notwithstanding broad acceptance that science alone cannot justify judgments about acceptable levels of risk, regulatory agencies such as EPA may find it expedient to cloak policy judgments under the guise of science. Professor Wendy

[11] (...continued)
1984, EPA endorsed these [NAS] distinctions between risk assessment and risk management for Agency use, and later relied on them in developing risk assessment guidelines.") (endnotes omitted) [hereinafter *EPA Risk Characterization Guidance*]; EPA, 61 Fed. Reg. 17,960, 17,960 (Apr. 23, 1996) (citing NAS report in adopting risk assessment guidelines "to ensure that the risk assessment process was maintained as a scientific effort separate from risk management.").

Wagner has dubbed this practice a "science charade," which occurs when "agencies exaggerate the contributions made by science in setting [environmental] standards in order to avoid accountability for the underlying policy decision."[12]

Professor Wagner identified several political, legal and institutional incentives for agencies to engage in the science charade by exaggerating the role and capability of science in making environmental decisions. *Id.* at 1650-73. For example, the strong deference that reviewing courts give EPA's scientific determinations creates "strong and virtually inescapable incentives to conceal policy choices under the cover of scientific judgments and citations." *Id.* at 1663. Professor Wagner identified previous NAAQS rulemakings as examples of a science charade. *Id.* at 1640-44.

II. SCIENCE ALONE CANNOT PROVIDE A BASIS FOR THE OZONE AND PM NAAQS

Science is central to evaluating the health risks of possible alternative air quality standards, but the decision of which standard to adopt is a risk management determination. As such, standard-setting should utilize all the available scientific evidence on health effects, but also needs to incorporate policy considerations. Scientific data on ozone and particulate matter do not and cannot, without more, provide a principled justification for the level at which the respective NAAQS are set.[13]

[12] Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COL. L. REV. 1613, 1617 (1995).

[13] *See* Congressional Testimony of John D. Graham, Director of Harvard Center for Risk Analysis, on Clean Air Act Reauthorization (Oct. 14, 1999) (1999 WL 27595650) ("scientific information (alone) does not typically provide an intelligible basis for the setting of safe (yet non-zero) amounts of air pollution.").

A. Science Alone Cannot Guide Standard-Setting for Non-Threshold Air Pollutants

The scientific data for ozone and PM indicate a continuum of health effects down to background (or natural) concentrations of the pollutant in the air, at which point the health effects associated with the pollutants cannot be distinguished from effects caused by other factors. There appears to be no clear demarcation of a discrete threshold below which a standard could be set to avoid all health effects.[14] EPA acknowledges that there is probably no threshold level for ozone below which no health effects would be expected to occur:

> The Administrator's decision to propose the level of an 8-hour primary O_3 standard at 0.08 ppm ... necessarily reflected a recognition ... that it is likely that O_3 may elicit a continuum of biological responses down to background concentrations.... Thus, in the absence of any discernable threshold, it is not possible to select a level below which absolutely no effects are likely to occur. Nor does it seem possible, in the Administrator's judgment, to identify a level at which it can be concluded with confidence that no "adverse" effects are likely to occur.

62 Fed. Reg. at 38,863 (citation omitted). EPA further acknowledged that "no standard within the range of levels and forms considered in this review, including the selected standard

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[14] Science can provide a distinct starting point for standard-setting for a pollutant for which the scientific evidence indicates a threshold in the exposure-response relationship, although the decision to set the standard at or below the threshold is itself a policy rather than scientific determination. In such cases, the Administrator can focus on how far below the threshold to set the standard to achieve an "adequate margin of safety," which also is a policy decision.

is risk-free, due to the continuum of risk likely posed by exposures to ambient O_3 potentially down to background levels." *Id.* at 38,873.[15]

Given a continuum of health effects, science provides information on the frequency and severity of adverse effects at various levels, but this information by itself does not identify the level at which to set the standard. For non-threshold pollutants, the only standard that could conceivably protect against all health effects would be a standard set at the level of zero, an option that EPA has explicitly ruled out. *E.g.*, 62 Fed. Reg. at 38,863 ("a zero-risk standard is neither possible nor required by the Act").

EPA's own Clean Air Scientific Advisory Committee concluded with respect to ozone that "there is no bright line which distinguishes any of the proposed standards (either the level or the number of allowable exceedences) as being significantly more protective of health" and "[c]onsequently, the selection of a specific level and number of allowable exceedences is a *policy* judgment."[16] In testimony to Congress, the Chair of CASAC reiterated that "the decisions to select a given level or number of allowable exceedences within their proposed ranges cannot be based on science;" rather, the

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[15] *See also id.* at 38,867 ("Clearly, for pollutants, such as O_3, that have no discernable thresholds for health effects, no standard can be risk-free."). With respect to particulate matter, EPA similarly noted that "the single most important factor influencing the uncertainty associated with the risk estimates is whether or not a threshold concentration exists below which PM-associated health risks are not likely to occur." 62 Fed. Reg. at 38,656. The Agency also recognized that the alternative PM standards it considered "will not be risk-free." *Id.*

[16] Closure Letter from George T. Wolff, Chair, Clean Air Scientific Advisory Committee, to Administrator Carol M. Browner (Nov. 30, 1995), at 3 (EPA-SAB-CASAC-LTR-96-002) (emphasis added).

selection of a particular standard is "strictly a policy judgment."[17]

B. EPA's Exclusive Reliance on Science to Justify its Standards Creates the Appearance of a "Charade"

In its brief filed in this Court, as well as in the proceedings below, EPA has defended its selection of its revised ozone and PM NAAQS based solely on scientific grounds. *See* pp. 2-3, *supra*. In addition, EPA suggests that this Court should be highly deferential to its selection of NAAQS standards precisely because it is a "scientific determination."[18] EPA's justification for its NAAQS standards appears to fit the pattern of what has been called a "science charade," in which an agency attempts to use science to justify its standards, even though the level and form of the standards is not something that science alone can determine.

Scholars have suggested that EPA has not been forthright in justifying its selection of current and past NAAQS standards based solely on science, when the selection of such a standard necessarily depends on risk management value judgments.[19]

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[17] Written Statement of George T. Wolff, Chair, EPA's Clean Air Scientific Advisory Committee's Panels on Ozone and PM, for the House Comm. on Health and Env't, Subcomm. on Oversight and Investigations (Apr. 10, 1997) (1997 WL 10569483).

[18] EPA Br. at 27 ("When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.") (quoting Baltimore Gas & Elec. Co. v. NRDC, 462 U.S. 87, 103 (1983)).

[19] Wagner, *supra* note 12, at 1640-44 (EPA's reliance on scientific and medical evidence alone to justify its previous ozone NAAQS is a "vivid illustration" of an "intentional science charade"); R. SHEP MELNICK, REGULATION AND THE COURTS: THE CASE OF THE CLEAN AIR ACT 261 (1983) ("There is, in short, no simple answer to the question of how the EPA sets air quality standards. Medical evidence cannot offer definitive guidance.... The EPA itself has refused to deal with the problem in a (continued...)

Professor David Faigman, for example, has recently argued that the "real loser in the PM/ozone drama was candor":

> The debate was phrased almost entirely in terms of science when the science played a decidedly minor role in the actual decision.... Science should not be used to hide what are essentially the true bases for decision.[20]

Amici do not purport to know the "true bases" of EPA's selection of its NAAQS, only that science alone cannot provide a consistent and principled basis for its standard-setting.

EPA claims to exclude, for example, considerations of costs and feasibility in setting air quality standards. However, as Professor Joseph Feller, a former EPA attorney, has written, "[i]f all costs are truly ignored, then no risk would be acceptable."[21] Scholars and commentators from a diverse range of viewpoints have argued that EPA does consider costs in setting its air quality standards, even though it excludes consideration of costs in its public justification for its standards.[22] Dr. John Graham, Director of the Harvard Center

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[19] (...continued)
forthright manner, hiding its policy choices behind its interpretation of scientific evidence."); Graham, *supra* note 13 ("When multi-billion dollar rulemaking decisions are made, it is inevitable that regulators will consider the consequences of their actions as well as the reasonableness of the relationship between risks, benefits and costs.").

[20] DAVID L. FAIGMAN, LEGAL ALCHEMY: THE USE AND MISUES OF SCIENCE IN THE LAW 187 (1999).

[21] Joseph M. Feller, *Non-Threshold Pollutants and Air Quality Standards*, 24 ENVTL. LAW 821, 833 (1994).

[22] *E.g.*, FAIGMAN, *supra* note 13, at 183 ("In practice, therefore, despite the legal technicality limiting EPA to promulgating regulations solely to promote health, costs are an integral part of the policy-making process at EPA."); MELNICK, *supra* note 12, at 297 ("[R]egulators inevitably consider cost [in setting air quality standards]. But presently they cannot explain (continued...)

for Risk Analysis, has further argued that EPA's "legal fiction" that it does not consider costs when setting NAAQS is "dysfunctional" because "it (1) reduces political accountability for value judgments and political choices, [and] (2) hides from public scrutiny claims that are made about risks, benefits and costs (since such claims are driven 'underground' in the course of regulatory deliberations)." Graham, *supra* note 13.

EPA's exclusive reliance on science to justify its standard selection thus creates the appearance that the Agency is using science to shield its decision-making from scrutiny. *See* Wagner, *supra* note 12, at 1656 (agencies may be able to find refuge from controversial public debates by relying on the

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[22] (...continued)
how they do."); MARC K. LANDY, MARC J. ROBERTS & STEPHEN R. THOMAS, THE ENVIRONMENTAL PROTECTION AGENCY: ASKING THE WRONG QUESTIONS 238 (1990) ("[I]n the absence of any threshold for risk, some balancing between costs and benefits had to be implicit in the standard setting decision – a reality EPA neither acknowledged nor forced the Congress to confront."); George Eads, *The Confusion of Goals and Instruments: The Explicit Consideration of Cost in Setting National Ambient Air Quality Standards*, in MARY GIBSON (ed.), TO BREATHE FREELY: RISK, CONSENT, AND AIR 222, 229 (1985) (it is a "policy fiction" that costs are not considered in setting NAAQS); Oren, *supra* note 7, at 10,662 ("EPA inevitably must therefore consider costs in standard-setting to help decide how stringent to make the standards."); THOMAS O. MCGARITY, REINVENTING RATIONALITY 253 (1991) ("The institution has considered costs and benefits, and the advice that the Administrator receives orally from subordinates reflects those considerations."); Gary E. Marchant, *Turning Two Blind Eyes: The EPA's Failure to Consider Costs and Health Benefits in Revising the Ozone Standard*, 11 Tul. Envtl. L.J. 261, 267-68 (1998) (EPA failed "to 'come clean' about the true nature of its decision-making"); C. Boyden Gray, *The Clean Air Act Under Regulatory Reform*, 11 TUL. ENVTL. L. J. 235, 235 (1998) ("The plain fact is that the EPA has for a long time considered costs and benefits in setting ambient standards–only it has done so behind closed doors...."); Cass R. Sunstein, *Is the Clean Air Act Unconstitutional?*, 98 MICH. L. REV. 303, 317-318 (1999) ("Only insiders know for certain whether EPA does in fact consider costs in issuing national ambient air quality standards," but evidence suggests that "costs do matter in the context of standard-setting for nonthreshold pollutants.").

science charade); MELNICK, *supra* note 12, at 297 ("Far from opening agency decisionmaking to public view, the courts have allowed and encouraged the EPA to sustain a myth and to keep secret its bureaucratic motives."). More significantly, such reliance prevents the Agency from including the careful and open consideration of relevant policy considerations in its justification for its air quality standards.

III. PRINCIPLED STANDARD-SETTING REQUIRES CONSIDERATION OF MORE THAN SCIENCE

The EPA has available to it several alternative approaches by which it could incorporate policy considerations into the reasons it provides for setting and revising NAAQS. Such alternative approaches have been relied upon by the EPA and other agencies in other contexts and have been endorsed in the risk management literature. By adopting one or more of these approaches and openly addressing the policy choices reflected in each, EPA can provide a more principled and consistent explanation for its air quality standards.

The Agency could begin by establishing an acceptable risk level as its core policy criterion. For example, EPA has defined "acceptable risk" for hazardous air pollutants based on a maximum individual mortality risk of no greater than 1 in 10 thousand. 54 Fed. Reg. 38,044 (Sept. 14, 1989). The agency has similarly set acceptable risk levels to guide its decision making under other statutes.[23] To be sure, extending this "acceptable risk" approach to NAAQS will be complicated by the diverse range of types and severity of health effects

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[23] The Agency has defined acceptable risk targets under the Clean Water Act, the Comprehensive Environmental Response, Compensation and Liability Act ("Superfund"), the Resource Conservation and Recovery Act, the Federal Insecticide, Fungicide & Rodenticide Act, and the Safe Drinking Water Act. *See generally* March Sadowitz & John D. Graham, *A Survey of Residual Cancer Risks Permitted by Health, Safety and Environmental Policy*, 6 RISK 17 (1995).

attributed to ozone or PM exposure. Moreover, using such an approach would mean that the acceptable risk level would become the standard no matter what the costs of achieving it. Nevertheless, if the Agency chose to pursue such an approach in order to establish an intelligible principle for setting air quality standards, it could then apply its acceptable risk criterion to select the least burdensome standard that results in an acceptable level of risk.[24]

Alternatively, the Agency could find a principle for standard-setting in the comparison of the adverse health and environmental effects of pollutants to any countervailing, beneficial effects of those pollutants (such as screening out harmful ultraviolet radiation).[25] The Agency would thereby select a level that minimizes overall risk. In such instances of risk-risk tradeoffs, the Agency would combine scientific information about risk with policy judgment about how best to resolve the tradeoff. *See generally* JOHN D. GRAHAM & JONATHAN B. WIENER, RISK VS. RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT (1995).

Another option is for the Agency to consider the full range of costs, beyond countervailing health risks, that can be anticipated to arise from a proposed standard. The Agency could use these broader estimates of costs to balance against estimated benefits in determining the level at which to set a standard. As already noted, it may be that EPA already tacitly

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[24] Comparative risk analysis may also be helpful in deciding acceptable risk levels, in which the Agency would compare ozone or PM risks to similar risks from other causes. *See generally* J. CLARENCE DAVIES, COMPARING ENVIRONMENTAL RISKS (1996).

[25] The Court of Appeals found that EPA had failed to consider such risk-risk tradeoffs in setting its ozone standards. American Trucking Associations, Inc. v. U.S. Environmental Protection Agency, 175 F. 3d 1027, 1052 (D.C. Cir. 1999). Because it did not seek review of that holding by this Court, EPA is required to consider such risk-risk tradeoffs on remand.

takes costs or feasibility considerations into account. By openly incorporating the use of economic analysis into its decision making, the EPA could provide a consistent basis for setting particular air quality standards. As a group of distinguished economists has collectively noted, "[t]he estimation of benefits and costs of a proposed regulation can provide illuminating evidence for a decision, even if precision cannot be achieved."[26] In the case of non-threshold pollutants, consideration of costs would not only be illuminating but also is probably inevitable.[27] Open deliberation of both benefits and costs by the Agency would provide a principled basis for setting air quality standards.[28]

Finally, as with costs, the Agency could incorporate into its decision-making explicit and detailed considerations of issues of equity. It would be relevant to risk management decisions for the Agency to consider how the effects of alternative standards may be distributed within society, such as whether health risks are differentially distributed across different racial and socio-economic groups.[29]

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[26] Kenneth J. Arrow, Maureen L. Cropper, George C. Eads, Robert W. Hahn, Lester B. Lave, Roger G. Noll, Paul R. Portney, Milton Russell, Richard Schmalensee, V. Kerry Smith, and Robert N. Stavins, *Is There a Role for Benefit-Cost Analysis in Environmental, Health, and Safety Regulation?*, 272 SCIENCE 221(1996).

[27] Sunstein, *supra* note 22, at 378 ("The problem is that it is impossible to assess 'safety' in a cost vacuum. In general cost-benefit analysis should be followed, acknowledging that it will raise some hard questions of value.")

[28] *See* Edward W. Warren & Gary E. Marchant, *"More Good Than Harm": A First Principle for Environmental Agencies and Reviewing Courts*, 20 ECOL. L. Q. 379 (1993).

[29] NATIONAL RESEARCH COUNCIL, UNDERSTANDING RISK, supra note 6, at 40 (noting that "[f]or some interested and affected parties in risk decisions, managing environmental risks has become a question of fairness, moral responsibility, and distributional equity.")

EPA's current approach, purporting to rely exclusively on scientific evidence of adverse health effects, has precluded it from openly adopting alternative approaches that would provide a more reasoned basis for guiding its policy judgment. As with any risk management decision, to justify air quality standards in a principled manner the EPA should expressly consider policy criteria such as acceptable risk, costs, risk-risk tradeoffs, or equity in addition to all the available science.

CONCLUSION

The lower court's conclusion that EPA "offers no intelligible principle by which to identify a stopping point" (175 F.3d at 1037) is well supported by an understanding of the appropriate role that science is able to play in risk management decision making. While science can identify the level and severity of the health effects from different levels of exposure to ozone or PM in various populations, science alone cannot establish what is acceptable for society.

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APPENDIX

IDENTIFICATION OF *AMICI*

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